

**FEE TRANSMITTAL**

Application Number 09/857,873  
Filing Date October 5, 2001  
Confirmation No. Unknown  
Inventor(s) John P. McKearn et al.  
Attorney Docket Number PHA 4293 (3167/4Z)

Art. Unit 1614  
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**AUG 18 2003**


**METHOD OF PAYMENT** **TECH CENTER 1800/2900**

1. ☐ The Commissioner is hereby authorized to charge the indicated fees to Deposit Account No. 19-1345.
- ☐ The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 to Deposit Account No. 19-1345.
- ☐ Applicant claims small entity status.
- \* 2. ☒ Check Enclosed. The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

**FEE CALCULATION**

1. ☐ BASIC FILING FEE Subtotal (1) \$ \_\_\_\_\_  
(Type: \_\_\_\_\_)
2. ☐ EXTRA CLAIM FEES Subtotal (2) \$ \_\_\_\_\_  
Total Claims \_\_\_\_\_  
Independent Claims \_\_\_\_\_  
Multiple Dependent Claims \_\_\_\_\_
3. ☒ ADDITIONAL FEES Subtotal (3) \$ 180.00
- ☐ Surcharge - late filing fee or oath  
☐ Surcharge - late provisional filing fee or cover sheet  
☐ Extension for reply within \_\_\_\_\_ month  
☐ Notice of Appeal  
☐ Filing a Brief in Support of an appeal  
☐ Request for ex parte Reexamination  
☐ Petitions to the Commissioner  
☒ Submission of Information Disclosure Statement  
☐ Recording each patent assignment per property  
☐ Request for Continued Examination  
☐ Other: \_\_\_\_\_

**TOTAL AMOUNT OF PAYMENT** \$ 180.00

  
Kathryn J. Doty, Reg. No. 40,593  
August 13, 2003  
Date

KJD/msc

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PHA 4293 (3167/4Z)  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of John P. McKearn et al. Art Unit 1614  
Serial No. 09/857,873  
Filed October 5, 2001  
Confirmation No. Unknown  
For METHOD OF USING CYCLOOXYGENASE-2 INHIBITOR AND ONE OR MORE  
ANTINEOPLASTIC AGENTS AS COMBINATION THERAPY IN THE  
TREATMENT OF NEOPLASIA

August 13, 2003

COMMISSIONER FOR PATENTS  
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**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit copies of the references listed on the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein.

Please note that Applicants make no representation as to the accuracy or completeness of the translations of the abstracts submitted herewith.

In preparation of this Information Disclosure Statement, Applicants determined that approximately 785 references were cited in the application. This review eliminated any reference that was determined to be irrelevant or merely cumulative. If the Office would like a copy of the eliminated references, they can be provided at the Office's request.

08/15/2003 ZJHAR1 00000070 09857873

01 FC:1806

180.00 DP

\* A check in the amount of \$180.00 is enclosed to cover the fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement. The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

\* Also enclosed is Applicants' executed Power of Attorney.

Respectfully submitted,



Kathryn J. Doty, Reg. No. 40,593  
SENNIGER, POWERS, LEAVITT & ROEDEL  
One Metropolitan Square, 16th Floor  
St. Louis, Missouri 63102  
(314) 231-5400

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PTO/SB/08A				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	09/857,873
				Filing Date	October 5, 2001
				Confirmation Number	Unknown
				First Named Inventor	John P. McKeane et al.
				Group Art Unit	1614
				Examiner Name	Unknown
Sheet	1	of	12	Attorney Docket No.	PHA 4293 (3167/4Z)

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	1.	4,100,274		Dutta et al.	07-11-1978
	2.	4,105,681		Bollag et al.	08-08-1978
	3.	4,140,707		Cleare et al.	02-20-1979
	4.	4,215,215		Bollag et al.	07-29-1980
	5.	4,310,666		Zee-Cheng et al.	01-12-1982
	6.	4,472,382		Labrie et al.	09-18-1984
	7.	4,596,797		Schweikert et al.	06-24-1986
	8.	5,250,683		Holton et al.	10-05-1993
	9.	5,254,703		Holton	10-19-1993
	10.	5,272,171		Ueda et al.	12-21-1993
	11.	5,319,112		Kingston et al.	06-07-1994
	12.	5,344,991		Reitz et al.	09-06-1994
	13.	5,455,270		Kaplan et al.	10-03-1995
	14.	5,633,016		Johnson	05-27-1997
	15.	5,686,419		Powers et al.	11-11-1997
	16.	5,696,131		Baguley et al.	12-09-1997

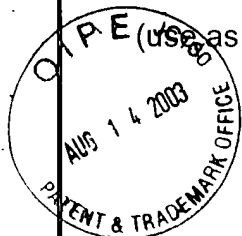
Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached.

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PTO/SB/08A				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	09/857,873
				Filing Date	October 5, 2000
				Confirmation Number	Unknown
				First Named Inventor	John P. McKearn et al.
				Group Art Unit	1614
				Examiner Name	Unknown
Sheet	2	of	12	Attorney Docket No.	PHA 4293 (3167/4Z)



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	17.	5,733,909		Black et al.	03-31-1998
	18.	5,767,142		LaVoie et al.	06-16-1998
	19.	5,824,699		Kreft et al.	10-20-1998
	20.	5,837,696		Golub et al.	11-17-1998
	21.	5,869,524		Failli	02-09-1999
	22.	5,952,381		Chen et al.	09-14-1999

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
	23.	DE	195 48 798	A1	Dr. Karl Thomae GmbH	07-03-1997	A
	24.	DE	196 13 933	A1	Merck Patent GmbH	10-09-1997	A
	25.	DE	196 26 701	A1	Hoechst AG	01-08-1998	A
	26.	EP	0 010 458	A1	ANVAR	04-30-1980	A
	27.	EP	0 054 168	A1	Klinge Pharma GmbH & Co.	06-23-1982	A
	28.	EP	0 095 875	A2	Farmos Group Ltd.	12-07-1983	
	29.	EP	0 165 904	A2	Ciba-Geigy AG	12-27-1985	A
	30.	EP	0 199 636	A1	C.I.R.D.	10-29-1986	A
	31.	EP	0 236 940	B1	Ciba-Geigy AG	09-16-1987	
	32.	EP	0 260 744	B1	Janssen Pharmaceutica N.V.	03-23-1988	

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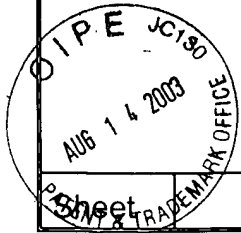
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	09/857,873
Filing Date	October 5, 2000
Confirmation Number	Unknown
First Named Inventor	John P. McKearn et al.
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket No.	PHA 4293 (3167/4Z)



Sheet 3

of

12

33.	EP	0 299 402	A2	ASTA Pharma Aktiengesellschaft	01-18-1989	A
34.	EP	0 331 983	A2	F. Hoffmann-La Roche AG	09-13-1989	A
35.	EP	0 402 232	A1	Rhone-Poulenc Sante	12-12-1990	A
36.	EP	0 532 156	A1	Matsuno et al.	03-17-1993	
37.	EP	0 579 915	A1	F. Hoffmann-La Roche AG	01-26-1994	A
38.	EP	0 702 962	A2	Eli Lilly and Company	03-27-1996	
39.	EP	0 703 239	A1	Hoechst Aktiengesellschaft	03-27-1996	A
40.	EP	0 716 086	A1	Boehringer Mannheim GMBH	06-12-1996	
41.	EP	0 743 070	A2	Trnka Mudr et al.	11-20-1996	A
42.	EP	0 758 649	A1	Kureha Chemical Industry Co., Ltd.	02-19-1997	
43.	EP	0 882 734	A2	F. Hoffman-La Roche AG	12-09-1998	
44.	EP	0 921 119	A1	ADIR Et Compagnie	06-09-1999	A
45.	GB	2 282 598	A	Merck & Co., Inc.	04-12-1995	
46.	WO	87/07609	A1	Taiho Pharmaceutical Co., Ltd.	12-17-1987	A
47.	WO	93/11145	A1	Banyu Pharmaceutical Co., Ltd.	06-10-1993	
48.	WO	93/18652	A1	Merck & Co.	09-30-1993	
49.	WO	94/12169	A1	Merck & Co., Inc.	06-09-1994	
50.	WO	94/13635	A1	Merck Frosst Canada Inc.	06-23-1994	
51.	WO	94/20480	A1	Merck Frosst Canada Inc.	09-15-1994	
52.	WO	94/21612	A1	Otsuka Pharmaceutical Co., Ltd.	09-29-1994	

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		Confirmation Number	Unknown	
		First Named Inventor	John P. McKearn et al.	
		Group Art Unit	1614	
		Examiner Name	Unknown	
Sheet	4	12	Attorney Docket No.	PHA 4293 (3167/4Z)

	53.	WO	94/25431	A1	The Wellcome Foundation Limited	11-10-1994	
	54.	WO	94/25466	A1	Glaxo, Inc.	11-10-1994	
	55.	WO	94/26731	A1	Merck Frosst Canada Inc.	11-24-1994	
	56.	WO	94/27980	A1	G.D. Searle & Co.	12-08-1994	
	57.	WO	95/02603	A2	Pharmacia S.P.A.	01-26-1995	
	58.	WO	95/08327	A1	The Government of the United States of America	03-30-1995	
	59.	WO	95/11883	A1	G.D. Searle & Co.	05-04-1995	
	60.	WO	95/12606	A1	The Wellcome Foundation Limited	05-11-1995	
	61.	WO	95/15316	A1	G.D. Searle & Co.	06-08-1995	
	62.	WO	95/24199	A2	Cell Therapeutics, Inc.	09-14-1995	
	63.	WO	95/30652	A1	G.D. Searle & Co.	11-16-1995	
	64.	WO	95/30656	A1	G.D. Searle & Co.	11-16-1995	
	65.	WO	96/00574	A1	Smithkline Beecham Corporation	01-11-1996	
	66.	WO	96/01653	A1	Board of Regents, The University of Texas System et al.	01-25-1996	
	67.	WO	96/03387	A1	G.D. Searle & Co.	02-08-1996	
	68.	WO	96/03392	A1	G.D. Searle & Co.	02-08-1996	
	69.	WO	96/06840	A1	Merck Frosst Canada Inc.	03-07-1996	
	70.	WO	96/14745	A1	The Regents of the University of California	05-23-1996	
	71.	WO	96/21667	A1	Merck Frosst Canada Inc.	07-18-1996	

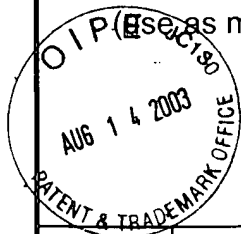
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				Group Art Unit	1614
				Examiner Name	Unknown
Sheet	5	of	12	Attorney Docket No.	PHA 4293 (3167/4Z)



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	72.	WO	96/33988	A1	Wisconsin Alumni Research Foundation	10-31-1996	
	73.	WO	96/35774	A2	The Children's Medical Center Corporation	11-14-1996	
	74.	WO	96/36335	A1	Pharmacia S.P.A.	11-21-1996	
	75.	WO	96/36612	A1	Rutgers, The State University of New Jersey	11-21-1996	
	76.	WO	96/36622	A1	Indena S.P.A.	11-21-1996	
	77.	WO	96/36623	A1	Merck Frosst Canada Inc.	11-21-1996	
	78.	WO	96/37469	A1	Merck Frosst Canada Inc.	11-28-1996	
	79.	WO	97/15666	A1	The Children's Medical Center Corporation	05-01-1997	
	80.	WO	97/15676	A2	Abbott Laboratories	05-01-1997	
	81.	WO	97/19954	A1	Asta Medica Aktiengesellschaft	06-05-1997	
	82.	WO	97/20835	A1	Harbor Branch Oceanographic Institution, Inc.	06-12-1997	
	83.	WO	97/24116	A2	Allergan	07-10-1997	
	84.	WO	97/29106	A1	Rutgers, The State University of New Jersey	08-14-1997	
	85.	WO	97/31936	A2	Wisconsin Alumni Research Foundation	09-04-1997	
	86.	WO	97/34608	A1	Mayo Foundation for Medical Education and Research	09-25-1997	
	87.	WO	97/36497	A2	Mars, Incorporated	10-09-1997	

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Sheet	6	of	12	Attorney Docket No.	PHA 4293 (3167/4Z)

	88.	WO	97/36863	A1	Merck Frosst Canada Inc.	10-09-1997	
	89.	WO	97/37658	A1	Boehringer Mannheim Italia S.P.A.	10-16-1997	
	90.	WO	97/41844	A1	Alcon Laboratories, Inc.	11-13-1997	
	91.	WO	97/47296	A2	Mount Sinai Hospital Corporation	12-18-1997	
	92.	WO	97/49704	A1	Janssen Pharmaceutica N.V.	12-31-1997	
	93.	WO	98/03484	A1	Merck Frosst Canada Inc.	01-29-1998	
	94.	WO	98/07433	A1	Bristol-Myers Squibb Company	02-26-1998	
	95.	WO	98/12181	A1	Rutgers, The State University of New Jersey	03-26-1998	
	96.	WO	98/13350	A1	Zeneca Limited	04-02-1998	
	97.	WO	98/14188	A1	Ilex Oncology Inc.	04-09-1998	
	98.	WO	98/16227	A1	G.D. Searle & Co.	04-23-1998	
	99.	WO	98/22101	A2	G.D. Searle & Co.	05-28-1998	
	100.	WO	98/25603	A1	Ilex Oncology, Inc.	06-18-1998	
	101.	WO	98/25896	A1	G.D. Searle & Co.	06-18-1998	
	102.	WO	98/40104	A2	Yale University et al.	09-17-1998	
	103.	WO	98/45294	A1	Astra Pharmaceuticals Ltd.	10-15-1998	
	104.	WO	99/01131	A1	Smithkline Beecham Corporation	01-14-1999	
	105.	WO	99/05104	A1	Pfizer Pharmaceuticals Inc.	02-04-1999	
	106.	WO	99/10331	A1	Abbott Laboratories	03-04-1999	

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Attorney Docket No.	PHA 4293 (3167/4Z)

Sheet 7 of 12

107.	WO	99/12930	A1	Glaxo Group Limited	03-18-1999
108.	WO	99/14194	A1	Merck Frosst Canada Inc.	03-25-1999
109.	WO	99/14205	A1	Almirall Prodesfarma S.A.	03-25-1999
110.	WO	99/21583	A1	Warner-Lambert Company	05-06-1999
111.	WO	99/23087	A1	Merck Frosst Canada & Co.	05-14-1999
112.	WO	99/31067	A1	Rutgers, The State University of New Jersey	06-24-1999
113.	WO	99/41241	A1	Rutgers, The State University of New Jersey	08-19-1999

**OTHER ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	114.	BARNI, S., et al., Clinical Efficacy of the Aromatase Inhibitor Anastrozole in Relation to Prolactin Secretion in Heavily Pretreated Metastatic Breast Cancer, Tumouri, Jan.-Feb. 1998, pp. 45-47, Vol. 84(1)	
	115.	BENSON, J.R., et al., Tamoxifen, Biologic Therapy of Cancer: Principles and Practice, 1997, pp. 817-828, Vol. One, Ch. 29, J.F. Holland et al. (Eds.), Baltimore, MD	
	116.	BREMBECK, F.H., et al., A Phase II Pilot Trial of 13-cis Retinoic Acid and Interferon- $\alpha$ in UICC Stage III/IV Pancreatic Cancer, Gastroenterology Oncology, April 1998, Abstract G2329, Vol. 114, No. 4, Pt. 2, A569	
	117.	BREMBECK, F.H., et al., A Phase II Trial of 13-cis Retinoic Acid and Interferon- $\alpha$ in Patients with Advanced Pancreatic Carcinoma, Cancer, 1998, pp. 2317-2323, Vol. 83, No. 11	
	118.	BROOKS, P.C., et al., Integrin $\alpha_v\beta_3$ Antagonists Promote Tumor Regression by Inducing Apoptosis of Angiogenic Blood Vessels, Cell, Dec. 30, 1994, pp. 1157-1164, Vol. 79	

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				Filing Date	October 5, 2003
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				First Named Inventor	John P. McKearn et al.
				Group Art Unit	1614
				Examiner Name	Unknown
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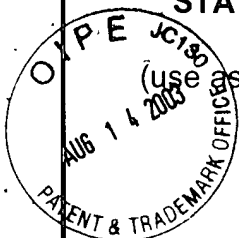
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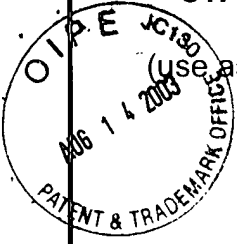
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